

MAY 4 1995

Food and Drug Administration
Washington DC 20204

John M. Mayhall, Jr.
President
Omega NutriPharm, Inc.
1000 Urban Center Parkway
Suite 450
Birmingham, Alabama 35242-2516

Re: Nutritional Support Statement Notification

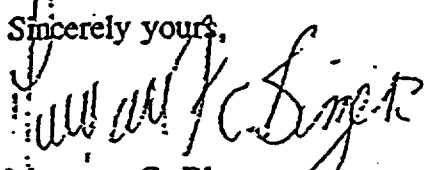
Dear Mr. Mayhall:

This acknowledges receipt on February 7, 1995, of your letter, dated February 3, 1995, notifying the Food and Drug Administration (FDA) that your Siberian ginseng dietary supplement product is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,


Margaret C. Binzer
Consumer Safety Officer
Regulatory Branch
Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0162

ACK4

Food and Drug Administration
Washington DC 20204

Steven R. Sumsion
General Counsel
NaturaLife
10 Mountain Springs Parkway
Springville, Utah 84663

May 4, 1995

Re: Nutritional Support Statement Notification

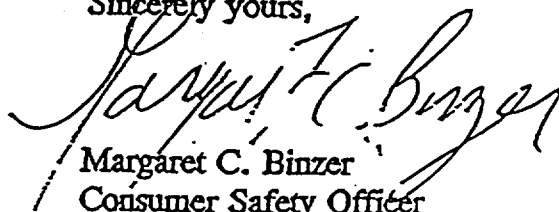
Dear Mr. Sumsion:

This acknowledges receipt on April 25, 1995 of your letter, dated April 21, 1995, notifying the Food and Drug Administration (FDA) that your dietary supplement product, cranberry powder capsules, is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,



Margaret C. Binzer
Consumer Safety Officer
Regulatory Branch
Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0162

ACK3

April 25, 1995

Steven R. Sumsion
General Counsel
Nature's Way Products, Inc.
10 Mountain Springs Parkway
Springville, Utah 84663

Re: Nutritional Support Statement Notification

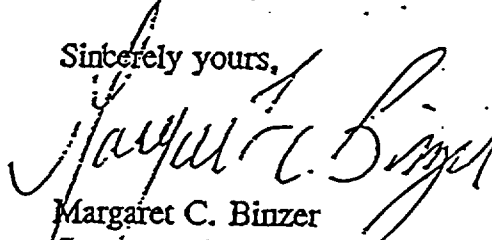
Dear Mr. Sumsion:

This acknowledges receipt on March 21, 1995, of your letter, dated March 15, 1995, notifying the Food and Drug Administration (FDA) that your cranberry powder capsules dietary supplement product is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,



Margaret C. Binzer
Consumer Safety Officer
Regulatory Branch
Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0162

ACK 2

NATURALIFE

April 21, 1995

Victor Fratelli, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Fratelli:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is cranberry powder capsules. The statement of nutritional support reads as follows:

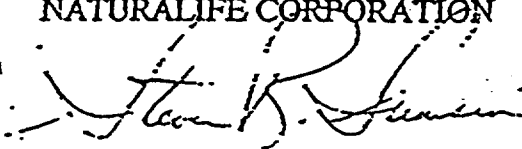
"Cranberry Fruit helps maintain a healthy urinary tract. Cranberry fruit helps maintain a healthy urinary tract by keeping harmful *E. coli* bacteria from sticking to the walls of the bladder."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURALIFE CORPORATION


Steven R. Sumsion
General Counsel

lre

Steve Letter (Fratelli) 5/1/95

10 Mountain Springs Parkway - Springfield, Utah 84663 - Phone: 801-489-1500 - Fax: 801-489-1700

975-0162

LET 12

Food and Drug Administration
Washington DC 20204

Patrick Mooney
Supernutrition Life-Extension Research, Inc.
2565 Third Street
San Francisco, California 94107

April 18, 1995

Re: Nutritional Support Statement Notification

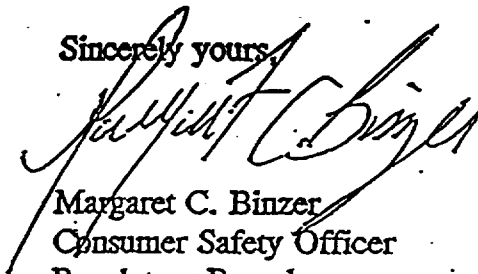
Dear Mr. Mooney:

This acknowledges receipt on March 10, 1995, of your letter, dated March 2, 1995, notifying the Food and Drug Administration (FDA) that your Opti-Packs dietary supplement, a multi-vitamin/multi-mineral daily dietary supplement in packets, is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,



Margaret C. Binzer
Consumer Safety Officer
Regulatory Branch
Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0162

ACK 1
Binzer

LEINER
HEALTH PRODUCTS

901 E. 233rd Street
Carson, California
90745-6204
310.835-8400
Fax 310/835-6615

April 5, 1995

Office of Special Nutritionals (HFS-450)
Center for Food Safety and
Applied Nutrition
Food & Drug Administration
200 C. Street, S.W.
Washington, DC 20204

SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, LEINER HEALTH PRODUCTS notifies FDA that it has begun using the following statement:

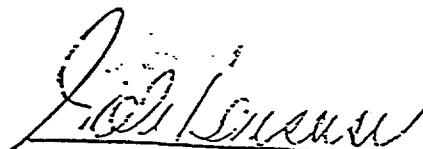
Certain phyto-chemicals such as lutein function as free-radical scavengers and help protect cell proteins, lipids and carbohydrates from oxidative damage.

on the following product(s):

Your Life® PHYTO-NUTRIENTS™ 500 mg SPINACH TABLETS

Very truly yours,

LEINER HEALTH PRODUCTS


Gale Bensussen
President

8395.017

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450
APR 12 12:55 '95

975-0162

LET II

LEINER
HEALTH PRODUCTS

901 E. 23rd Street
Carson, California
90745-6204
310/235-8400
Fax 310/835-6615

April 5, 1995

Office of Special Nutritionals (HFS-450)
Center for Food Safety and
Applied Nutrition
Food & Drug Administration
200 C. Street, S.W.
Washington, DC 20204

SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, LEINER HEALTH PRODUCTS notifies FDA that it has begun using the following statement:

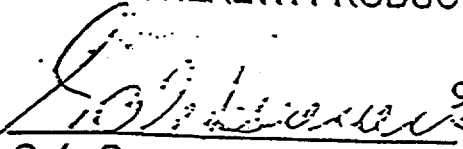
Coenzyme Q10 is found in high concentrations in the heart and muscles. It is used by every cell to produce ATP - or bioavailable energy. Like a vitamin, Coenzyme Q10 works in the body as a catalyst to convert fats and carbohydrates into energy. It also boosts Vitamin E's ability to destroy free radicals.

on the following product(s):

Your Life® Coenzyme Q10

Very truly yours,

LEINER HEALTH PRODUCTS


Gale Bensussen
President

95 APR 12 PM 12:56

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

JB95.014

975-0162

LET10